



*Rhode Island Department of Health*  
*Childhood Lead Poisoning Prevention Program*  
**PROCEDURE TO RELEASE DATA**

**Goals of this Document:**

1. To ensure that data requests are properly designed for efficient uses of available data
2. To ensure that all data requests are appropriately processed
3. To capitalize on resources and prioritize requests
4. To encourage research that promotes the responsible use and dissemination of these data

**A. NON-CONFIDENTIAL DATA REQUESTS**

**A.1. AGGREGATE DATA CURRENTLY AVAILABLE**

The Rhode Island Childhood Lead Poisoning Prevention Program (RI CLPPP) posts aggregate data, both current and historic, on the web for public use. These data should be used in the format and context that is provided. Please visit [www.health.ri.gov/lead/family/data.php](http://www.health.ri.gov/lead/family/data.php) if you would like to access the following information:

- a) Lead screening in Rhode Island children under the age of six
- b) Lead exposure among children entering kindergarten
- c) Prevalence of elevated blood lead levels in RI by city and town
- d) Prevalence of elevated blood lead levels by urban location
- e) Incidence of elevated blood lead levels in RI by city and town
- f) Incidence of elevated blood lead levels by urban location
- g) RI CLPPP's annual report "Childhood Lead Poisoning in Rhode Island, The Numbers"
- h) RI CLPPP's annual reports for each of the core cities

**A.2. OTHER AGGREGATE DATA**

For other aggregate data not available on the website, please complete and submit a data request form. There are two separate data request forms; one is for [non-confidential data](#) the other is for [confidential data requests](#) (Please refer to section B on page 3 of this manual before making a confidential data request). These forms can be found in the Resources section on page 6 of this manual. The requests will be reviewed as they are received, and will be completed in order of priority. Priority status will be determined by several factors, including, but not limited to:

complexity of the request, availability of the data, purpose of the request, time frame indicated in the request, and staff resources.

In cases where subgroups on which data is requested are relatively small, aggregate data requests may have to be treated as confidential. See the next pages for details.

Examples of these types of requests:

- a) Number of screened children in the city of Providence in fiscal year 1998, by age.
- b) Number of inspections performed in last 3 years that have status "open."

### **A.3. RAW DATA**

This refers to requests for raw data to be analyzed primarily outside of the Lead Program, and will be considered under the following conditions:

- Requested data doesn't include confidential information. If it includes confidential information (e.g., last name, street address or other item that can identify individuals), see section B of this document.
- The RI CLPPP approves purposes of the study/analysis/investigation.
- Data is currently collected and available on the database for a reasonable time period that allows study's goals to be achieved.
- Results and format of the analysis/investigation are presented to RI CLPPP for further discussions, modifications and acceptance prior to public release. In the absence of such acceptance, a disclaimer indicating the data came from HEALTH but analysis was done independently from the Rhode Island Department of Health must be included in the final documents containing data analysis results. (Example: "The authors acknowledge the assistance of the RI Department of Health in providing data used in this report. This assistance does not necessarily constitute an endorsement of the methods, opinions and conclusions in this report.")
- An agreement in terms of partnership and sharing resources to conduct data analysis exists, is current or is made between RI CLPPP and the entity requesting data.

### **A.4. PROCESS TO RELEASE NON-CONFIDENTIAL DATA REQUESTS**

The process for data requests is as follows:

1. Fill out the data request form, and submit it to the Program's Epidemiologist, as indicated in the Contact section, page 6 of this document.
2. The request will be forwarded to the unit handling the data and will be processed in order of priority.
3. Unless there are extenuating circumstances, a response will be provided within 10 business days.

## **B. CONFIDENTIAL DATA REQUESTS**

*The identity of any person (or any group of facts that tends to lead to the identity of any person) whose blood test result is submitted to the Rhode Island Childhood Lead Poisoning Prevention Program is confidential and shall not be open to public inspection or dissemination. Such information shall not be available for disclosure, inspection or copying under the U.S. [Freedom of Information Act](#) or under Rhode Island General Laws [Title 38- Chapter 2](#) (Access to Public Records). All information for specific research purposes may be released in accordance with procedures established by RI CLPPP.*

This section refers to data requests for purposes of epidemiological researchers and other studies, which require individually identifiable data. Examples of this type of request are:

- a) Names of children living in the city of Pawtucket and found with elevated lead levels of Pb >9 µg/dL during years 1997 and 1998.
- b) Addresses of lead poisoned children in a certain geographic location. Note that individually identifiable data may include data requests that don't request name or last name.

### **B.1. REQUEST FOR CONFIDENTIAL DATA**

Prior to completing a data request for confidential data, the investigator is encouraged to contact RI CLPPP to discuss the data needed to conduct the research. This preliminary discussion will ensure that the data that are available will support the study design, and that the data request is completed appropriately.

All requests by researchers for confidential data must be submitted in writing to the Lead Program's contact included on page 6 of this document. In order to consider a request, the investigator must submit the following:

1. A completed "Data Request Form". Additional information, such as a **study protocol**, may be submitted along with the completed Data Request Form. Use additional pages if necessary.
2. Methods for documenting compliance with: [Title 42 Part 2a of the Code of Federal Regulations \(CFR\)](#) (Public Health -Protection of Identity-Research Subjects), specifically, [42 CFR 2\(a\) 4\(a\) through \(j\)](#) (Contents of Application; in General), [42 CFR 2a.6\(a\) and \(b\)](#), (Issuance of Confidentiality Certificates; Single Project limitation), and [42 CFR 2a.7 \(a\) and \(b\)\(1\)](#); (Effect of Confidentiality Certificate.)

The RI CLPPP Lead Management Team will review and evaluate the request. If RI CLPPP approves the proposal, the researcher must obtain Institutional Review Board (IRB) approval through the RI Department of Health. The data will be released after this two-step approval process is complete. See below for more details.

### **B.2. RI CLPPP SCIENTIFIC REVIEW OF THE REQUEST**

All requests for confidential data will be reviewed by RI CLPPP. The review process will evaluate whether the following criteria were met:

- a) The request states goals or objectives,

- b) The request documents the feasibility of the study design in achieving the stated goals and objectives,
  - c) The request documents the need for the confidential data to achieve the stated goals and objectives,
  - d) The requested data can be provided within the time frame set forth in the request,
  - e) The request documents that the researcher has qualifications relevant to the type of research being proposed
  - f) The research will not duplicate other research efforts already in progress, particularly if the proposal involves contacting patients,
  - g) Other conditions necessary to evaluate the need for confidential data.
- No later than 30 days after the receipt of the proposal, RI CLPPP will issue a formal letter indicating whether the request was accepted, accepted with modifications, or not accepted. If the request is **accepted**, the researcher can continue with the process to seek IRB review (see section B.3).
  - If the request is **accepted with modifications**, the changes must be made and re-submitted to the RI CLPPP epidemiologist for approval before continuing with the process to seek IRB review.
  - If the request is **not accepted**, the researcher may revise the request and resubmitted it. In this case, the process must be repeated from the beginning.

Reasons for which a request may not be accepted include, but are not limited to, the following:

- Security measures to maintain the confidentiality of the data are unsatisfactory,
- Data requested is unavailable or unreliable,
- The stated purpose does not meet RI CLPPP's mission statement,
- RI CLPPP is unable to provide the data in the requested format,
- The applicant is not an accredited or licensed research institution, a government agency, university research center or private research firm, or,
- The information cannot be provided by the requested date.

### ***B.3. THE INSTITUTIONAL REVIEW BOARD (IRB) REVIEW***

For information on the IRB process and timeframes, please see the IRB protocol available at <http://www.health.ri.gov/topics/irb.php> or contact John Fulton at (401) 222-1172 ([john.fulton@health.ri.gov](mailto:john.fulton@health.ri.gov)) or Leonard Green at (401) 2227841([leonard.green@health.ri.gov](mailto:leonard.green@health.ri.gov)).

### ***B.4. ACCEPTANCE TO RELEASE CONFIDENTIAL DATA***

The Rhode Island Childhood Lead Poisoning Prevention Program will enter into information agreements for all approved research requests that have also been approved by the IRB. These agreements shall specify the information that is being released and how it can be used in accordance with the standards in the Scientific Review section. In addition, the researcher shall include an assurance that:

- a) Use of data is restricted to the specifications of the protocol,
- b) Any and all data which may lead to the identify of any patient, research subject, physician, other person, or hospital is strictly privileged and confidential and the researcher agrees to keep all such data strictly confidential at all times,
- c) All officers, agents and employees will keep all such data strictly confidential. The researcher will communicate the requirements of this section to all officers, agents and employees, will discipline all persons who may violate the requirements of this section, and will notify RI CLPPP in writing within 48 hours after any violation of this section, including full details of the violation and corrective actions to be taken,

- d) All data provided by the Program pursuant to the agreement may only be used for the purposes named in the agreement and that any other or additional use of the data may result in immediate termination of the agreement by the Department, and,
- e) All data provided by the program pursuant to the agreement is the sole property of RI CLPPP and may not be copied or reproduced in any form or manner, except for research use by the researcher, and that all data, copies and reproduction of the data made for the researcher's internal use shall be returned to RI CLPPP upon termination of the agreement.

Any departures from the approved protocol must be submitted in writing and approved by RI CLPPP in accordance with sub-sections c) and d) of this Section prior to initiation. No identifying information may be released by a researcher to a third party.

**Notes:**

- *The Childhood Lead Poisoning Prevention Program reserves the right to adjust, modify and/or update the present document at any time. Please contact us if you have questions about the information contained here.*
- *The data from the Childhood Lead Poisoning Prevention Program resides in the Lead Elimination Surveillance System (LESS) database.*
- *RI CLPPP requires that the source of the data is noted on any written publications, reports or documents where the lead data is included.*

## **DEFINITIONS**

**LEAD PROGRAM'S MANAGEMENT TEAM.** A team of Lead Program authorities formed by:

- Medical Director
- Epidemiologist
- Family Health Program Manager
- Environmental Lead Program Manager
- Environmental Health Toxicologist
- Laboratories representative(s)
- Data Manager(s)/IS designee

**RI CLPPP.** "Rhode Island Childhood Lead Poisoning Prevention Program"

**LESS.** The name of the Lead Program's database, "Lead Elimination Surveillance System."

**AGGREGATE DATA.** Data that makes it impossible to identify any patient, reporting entity or primary care giver. These data can be made available to the public pursuant to the Freedom of Information Act.

**CONFIDENTIAL DATA.** Data that can identify any patient, reporting entity or primary care giver, or clinical history, results of a test, etc. of a patient.

## **RESOURCES**

1. [Non-confidential data request form](#)
2. [Confidential data request form](#)
3. Rhode Island Department of Health's IRB protocol can be found at [www.health.ri.gov/topics/irb.php](http://www.health.ri.gov/topics/irb.php)
4. U.S. [Freedom of Information Act](#).
5. Rhode Island General Laws [Title 38- Chapter 2](#) (Access to Public Records).
6. [Title 42 Part 2a of the Code of Federal Regulations \(CFR\)](#) (Public Health -Protection of Identity- Research Subjects),
7. [42 CFR 2\(a\) 4\(a\) through \(j\)](#) (Contents of Application; in General).
8. [42 CFR 2a.6\(a\) and \(b\)](#), (Issuance of Confidentiality Certificates; Single Project limitation)
9. [42 CFR 2a.7 \(a\) and \(b\)\(1\)](#); (Effect of Confidentiality Certificate.)
10. Rhode Island General Law [Title 5 Chapter 37 Section 3-4](#)(Confidentiality of Health Care Communications and Information Act Section-4 Limitations on and permitted disclosures)

## **CONTACT**

Daniela Quilliam, MPH  
Epidemiologist, Office of Environmental Health Risk Assessment  
3 Capitol Hill - Room 201  
Providence, RI 02908-5097  
(401) 222-7730 FAX: (401) 222-6953  
email: [Daniela.Quilliam@health.ri.gov](mailto:Daniela.Quilliam@health.ri.gov)

Or visit our web site at <http://www.health.ri.gov/lead/>